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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,526	06/27/2001	Martin G. Crosby	UROMED-1	3190

23599 7590 04/21/2003

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EXAMINER

PATTEN, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 04/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/891,526

Applicant(s)

Crosby et al.

Examiner

Patricia Patten

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 3, 2003
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5, 13-20, and 25-34 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 13-20, 25-31, and 33 25-34 is/are rejected.
- 7) ☒ Claim(s) 32 and 34 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 11
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-3, 5, 13-20 and 25-34 are pending in the application and were examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 2, 3, 5, 13, 14, 15, 16, 17, 18, 19, 20, 25, 28, 29, 30, 31, 32, 33, 34 are newly rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 2, 3, 5, 13, 14, 15, 28, 29 and 30 either recite, depend upon a claim which recites, or incorporate all the limitations of a claim which recites 'lipophilic extract'. This term is considered New Matter as it was not disclosed in the Instant specification as originally filed. Applicant states that the 'lipophilic extract' was inherent to the teachings of US 4,118,508 which taught several types of extraction protocols for

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C.forskohlii (p. 6, Arguments). However, US 4,118,508 did not specifically recite 'lipophilic extract' and it is deemed that 'lipophilic extract' is not necessarily an 'inherent property' of US 4,118,508 as Applicants contend. What does 'lipophilic extract' mean? Obviously this means that lipids are present, but what lipids? What else does the extract comprise? There is no information/description/definition within the Instant specification nor US 4,118,508 to determine what a 'lipophilic extract' is, and therefore it is deemed that this phrase was not present in US 4,118,508 or the Instant disclosure at the time of filing. Therefore, this language has been considered New Matter.

Applicants are asked to delete the New Matter from the claims in order to overcome this rejection.

Claims 16-18 remain rejected and claims 31 and 33 are newly rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous office action. Claims 31 and 33 are drawn to wherein the *C.forskohlii* comprises about or at least 80% forskolin.

Applicants' arguments were fully considered, but not found persuasive.

Applicants' arguments with regard to this rejection are mainly that "There are no reasons given to doubt the accuracy of the asserted properties of the claimed subject matter...There is nothing of record to establish that without the *Coleus forskohlii* extract

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utilized in the examples, the invention would not work. This is mere speculation. This is totally insufficient to support an enablement rejection" (p. 5, Arguments).

Further, there are *no working examples* present in the Instant specification which demonstrate that any other combination of materials, besides the materials shown in example 2, will work commensurate in scope with the claimed invention. Thus, the Instant specification as filed is lacking critical information as to how the skilled artisan would use other combinations of ingredients to manifest the effects of the composition found in Example 2.

There is no evidence in the prior art that other combinations of the ingredients found in Example 2 will create an arousal response when administered topically to an individual. The lack of teachings in the prior art, the lack of teachings in the specification, along with the unpredictability of plant extracts as a whole would lead the skilled artisan to perform their experimentation without an expectation of success, thereby making the experimentation undue.

Claims 2, 3, 5, 13-15, 19, 20, 25, 28 and 30 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions

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and methods comprising an extract of *Coleus forskohlii* which contains 80% forskolin, does not reasonably provide enablement for *any* extract of *Coleus forskohlii*.

Applicants argue that 'Skilled workers readily know and appreciate the definite scopes of the various ingredients recited in the claims such as borage seed oil, Angelica species root, Coleus forskohlii extract, etc. Just because it is possible to obtain various kinds of extracts within the language employed in the claims does not mean that a skilled worker would have any difficulty formulating the included extracts or in testing them. Nor is the scope of each of the recited ingredients in any way unreasonably broad." (P.5, Arguments).

As evidenced by the previous office action, the medicinal characteristics of each possible plant extract is a priori unpredictable. Applicants contend that other extracts of C. Forskohlii will produce similar/analogous effects to the extract actually displayed in the Instant specification, however have not disclosed any other extracts which would actually perform analogously to the extract which contains 80% forskolin. Would an extract that contains 1% forskolin be effective in manifesting an arousal response in a mammal? The statute under 35 U.S.C. 112 First paragraph reads:

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The specification shall contain a written description of the invention, and of the manner and process of *making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same* and shall set forth the best mode contemplated by the inventor of carrying out his invention. (Emphasis added).

The unpredictability with regard to the medicinal nature of plant extracts was clearly explained in the previous office action. It was further determined that due to the vastness of potential extracts which could be performed on *C.forskohlii* coupled with the unpredictability of the medicinal aspects of each individual type of extract, the skilled artisan would necessarily need to perform undue experimentation, involving rigorous trial and error protocols to determine what other extracts besides the extract containing 80% forskolin are effective in manifesting an arousal response when applied topically. It was clearly stated in the previous office action that each individual extract has unique properties which will consequently result in varying pharmacological properties.

Claim Rejections - 35 USC § 103

Claims 1-3, 5, 13-15, 19, 26, 27, 28, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habib et al. (US 5,690,947) in view of Horrobin et al.

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(US 5,614,208), Oblong et al. (WO 00/69406), Kuniyoshi et al. (JP 405194179A-English Abstract) and Tian (CN 1104886A-Abstract).

Applicants' arguments were considered, however, not found convincing.

Applicant argues that 'The prior art rejection is ...untenable. The simple facts that ingredients are known and that they can or might be combined are absolutely insufficient to support a rejection" (p.6, Arguments). Applicants are asked to review *In re Kerkhoven*: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art".

Here, the emphasis is 'useful for the same purpose'. In the Instant claims drawn to a composition, the intended use of the composition is to be used topically. All of the prior art products were known individually for topical use. Therefore, it would have been *prima facie* obvious to combine the respective ingredients for topical use.

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It is noted that claims 31-34 are free of the art.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback is on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CHRISTOPHER R. TATE
PRIMARY EXAMINER